K062735

510(k) Summary

OCT 27 2006

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Invisible Technology (IV-Tech)
Nassa B/D 4F, 581 Shinsa-Dong
Kangnam-ku, Seoul Korea #135-892

Contact Person: Tae Hee, Cho

Date: September 12, 2006

807.92(a)(2)

Trade Name: TuTu 7

Common Name: Dental Curing Light

Classification Name(s): Ultraviolet Activator for Polymerization – 872.6070

Classification Number: EBZ

807.92(a)(3)

Predicate Device(s)

Dentsply International	SmartLite PS Pen-Style LED Curing Light	K041372
3M ESPE AG	Elipar FreeLight	K011154

807.92 (a)(4)

Device Description

The TuTu7 is a LED curing light that is small and easy to use, yet powerful and swift in curing. It has a compact, lightweight hand piece, with a curved and contoured tip, to allow the light to be positioned and applied anywhere in the oral cavity. The TuTu has 3 different functioning modes, continuous, pulse and ramp. The device peeps every 3 seconds for precise timing of exposure, regardless of mode setting. The rechargeable battery is a Lithium Ion, which at full charge can last up to 120 minutes. The TuTu is provided with a battery charger, which also acts as a storage holder for the device. A silicone sheath is provided to refract the light and protect the eyes of the operator.

807.92(a)(5)

Intended Use(s)

The TUTU ™ LED intraoral curing light is designed to polymerize visible light cure (VLC) dental materials including dental pit and fissure sealants, bonding adhesives, cements, restorative or luting materials

807.92(a)(6)

Technological Characteristics

	SmartLite PS LED Curing Light DENTSPLY K041372	Elipar FreeLight 3M ESPE AG K011154	TuTu 7 IV-Tech This Submission
Product Code	EBZ	EBZ	EBZ
CFR	872.6070	872.6070	872.6070
Wavelength Range n/m	450-475	430-480	380-480
Watts mW-cm	950	1200	1300
Battery Type	NMH	NHH	2,300 Li-on Battery
Weight	100g	220g	142g
Rotating Tip	Yes	No	No
Built in meter	No	Yes	No
Repl. Bulb	No	No	Yes
Multiple Curing Time	No	Yes	Yes
LED Blue Light	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2006

Invisible Technology Company, LTD
C/O Ms. Allison Scott
The Anson Group
11460 North Meridian Street, Suite 150
Carmel, Indiana 46032

Re: K062735
Trade/Device Name: TuTu 7
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: September 12, 2006
Received: September 13, 2006

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

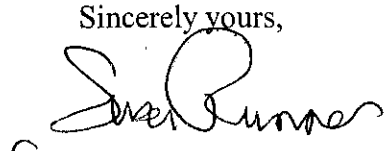
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,



for Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062735

Device Name:

Indications For Use:

The TUTU ™ LED intraoral curing light is designed to polymerize visible light cure (VLC) dental materials including dental pit and fissure sealants, bonding adhesives, cements, restorative or luting materials

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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